In the Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-789

SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION, ET AL., PETITIONERS

v.

PETER J. BRENNAN, SECRETARY, DEPARTMENT OF LABOR, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

MEMORANDUM FOR THE RESPONDENTS IN OPPOSITION

1. Petitioners contend that the court below applied an erroneous standard for reviewing a determination by the Assistant Secretary of Labor for Occupational Safety and Health, under Section 6 of the Occupational Safety and Health Act of 1971, 84 Stat. 1593, 29 U.S.C. 655, that the chemical ethyleneimine (EI) is carcinogenic. The determination resulted in the promulgation by the Secretary of a safety standard regulating worker exposure to solid or liquid mixtures containing one percent or more of the chemical (Pet. App. 36a-49a). The standard, one of a group regulating fourteen chemical carcinogens, was issued pursuant to Sections 6(b) and (c) of the Act.[1]

[1]A temporary emergency standard issued pursuant to 29 U.S.C. 655(c) had earlier been vacated by the court of appeals for failure of the Secretary adequately to state his reasons for issuing the standard. *Dry Color Manufacturers' Association* v. *Department of Labor*, 486 F.2d 98 (C.A. 3).

The Secretary's determination was premised upon the criterion that substances shown to cause cancer in two animal species are to be treated as posing an impermissible danger of cancer to man "until evidence to the contrary is produced" (Pet. App. 8a, 27a).[2] On the basis of scientific studies in the record showing that EI caused cancer in mice and rats (Pet. App. 25a), therefore, the Secretary ordered that EI be regulated as a potential human carcinogen.

On review, the court of appeals sustained the EI standard, except for certain provisions involving use of EI in laboratories as to which the court vacated and remanded the Secretary's order (Pet. App. 10a-11a).

In affirming the propriety of the Secretary's rebuttable determination of human carcinogenicity on the basis of animal experiments, the court of appeals noted the difficulty of reviewing what was essentially a policy choice by the Secretary incapable of factual certainty. The court nevertheless scrutinized the Secretary's determination according to the following guidelines (Pet. App. 10a):

> judicial review of a § 6 standard properly includes at least the following:
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> (1) determining whether the Secretary's notice of proposed rule making adequately informed interested persons of the action taken;
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> (2) determining whether the Secretary's promulgation adequately sets forth reasons for his action;
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> (3) determining whether the statement of reasons reflects consideration of factors relevant under the statute;
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> (4) determining whether presently available alternatives were at least considered; and

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[2] "Pet. App." refers to petitioners' appendix filed in this Court. "App." refers to the joint appendix filed in the court of appeals.

(5) if the Secretary's determination is based in whole or in part on factual matters subject to evidentiary development, whether substantial evidence in the record as a whole supports the determination.

Applying these tests, the court of appeals vacated the Secretary's EI standard as applied to laboratory subsection because of lack of adequate notice, but concluded as to the remainder of the standard that the statement of reasons given by the Secretary in the preamble to the standard (Pet. App. 21a-36a) adequately reflected the relevant statutory considerations and that "there does exist substantial evidence in the record as a whole to support the Secretary's finding that EI is carcinogenic in rats and mice and in the absence of evidence of carcinogenicity in humans, the Secretary properly weighed the only available alternatives" (Pet. App. 11a).

2. Petitioners point out that Section 6(f) of the Act, which governs informal rulemaking proceedings, provides that "[t]he determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole." There is no doubt, however, that the Secretary's factual determination that EI causes cancer in rats and mice was supported by substantial evidence. One study, carried out in 1954, concluded that EI may be regarded as carcinogenic in rats and mice (Pet. App. 7a). A second study, in 1969, concluded that mice under experimental exposure to EI developed tumors with "malignant potentiality" (*ibid.*).

In the absence of reliable data on the carcinogenic effect of EI upon humans, the Secretary made a reasonable inference on the basis of the foregoing determination about its effect upon mice and rats. Such inferences are necessary and appropriate to enable the Secretary to

assure "the greatest protection of the safety or health of the affected employees," as the Act requires. 29 U.S.C. 655(a). Section 6(b)(5) of the Act, 29 U.S.C. 655(b)(5) directs that:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents * * * shall set the standard which most adequately assures, to the extent feasible, on the basis of the *best available evidence*, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. [Emphasis supplied.]

Here, data about EI's effect upon mice and rats provided the "best available evidence" of its predictable effect upon humans. Under the Act "it remains the duty of the Secretary to act to protect the workingman, and to act even in circumstances where existing methodology or research is deficient." *Society of the Plastics Industry, et. al.* v. *Occupational Safety and Health Administration, et. al.*, C.A. 2, Nos. 74-2284, 74-2286, 74-2308, 74-2345, 74-2429, 74-2450, 74-2491, 74-2285, 74-2609, decided January 31, 1975, slip op. 1566.

Moreover, the reasonableness of the Secretary's inference here is supported by substantial opinion in the scientific community. This is shown by the Report of the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens to the Surgeon General, noted by the court of appeals (Pet. App. 7a), which concluded that "[a]ny substance which is shown conclusively to cause tumors in animals should be considered carcinogenic and therefore a potential cancer hazard for man" and that "the implication of potential

[human] carcinogenicity should be drawn from [animal] tests resulting in the reduction of benign tumors" as well as malignant ones (App. 330).[3]

Contrary to petitioners' assertions, there is no conflict among the circuits on the scope of review issue. The courts of appeals that have addressed the problem of applying a substantial evidence standard to informal rulemaking proceedings are in agreement that in promulgating such rules the Secretary must stay within the rulemaking record, and to the extent he finds *facts* they must be supported by substantial evidence. To the extent that the Secretary exercises what is more akin to legislative judgment, however, his determinations must be reasonable, in light of the statutory policies he is charged with effectuating. See, *e.g.*, *Society of the Plastics Industry, et. al.* v. *Occupational Safety and Health Adminstration, et al., supra*; *National Roofing Contractors Ass'n* v.

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[3]It is also shown by the NIOSH Hazard Review, summarizing and evaluating all published literature on EI, which *inter alia* concludes that numerous studies have indicated EI's mutagenic effects, that this substance's power to produce cancer in animal species in controlled laboratory conditions has been amply demonstrated, and that "extrapolation to humans of the findings in two separate, controlled animal studies" was compatible with accepted practice" (App. 942ff); by expert testimony that induction of animal tumors is *per se* proof of carcinogenicity (App. 3061, 3066, 3068); and by the fact that in 1972 the American Conference of Government Industrial Hygenicists recommended a zero human exposure level for EI because it had "induced cancer in animals under appropriate experimental conditions" (App. 984, 985).

Contrary to petitioner's assertions, their introduction of an unpublished epidemiological study purporting to show EI produced no harmful effects in exposed workers does not rebut this evidence. That study was criticized by epidemiological experts as "entirely meaningless" and providing "no scientific basis for making a valid determination of comparative mortality" (Appellee's Brief regarding EI, Addendum 2a-5a; App. 1564-1565).

Brennan, 495 F.2d 1294, 1298-1299 (C.A. 7), certiorari denied, January 13, 1975, No. 74-276; *Florida Peach Growers Ass'n* v. *Department of Labor*, 489 F.2d 120, 128-129 (C.A. 5); *Industrial Union Department, AFL-CIO* v. *Hodgson*, 499 F.2d 467, 472-476, 478-488 (C.A.D.C.); *Associated Industries of New York State, Inc.* v. *Department of Labor*, 487 F.2d 342, 349-350, 351-354 (C.A. 2).[4] Regardless of whether the courts term this requirement of rationality one of requiring "substantial evidence," or avoiding abuse of discretion, we submit that "the controversy is semantic * * * [and] lacks * * * dispositional importance" (*Associated Industries of New York State, Inc.* v. *Department of Labor, supra*, 487 F.2d at 349).

For the foregoing reasons, it is respectfully submitted that the petition for a writ of certiorari be denied.

ROBERT H. BORK,
Solicitor General.

WILLIAM J. KILBERG,
Solicitor of Labor,

BENJAMIN W. MINTZ,
Associate Solicitor for Occupational Safety and Health,

MICHAEL H. LEVIN,
Counsel for Appellate Litigation, Department of Labor.

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[4]Indeed, any potential conflict has been eliminated by the Second Circuit's recent decision in *Society of Plastics Industry, et. al.* v. *Occupational Safety and Health Administration, et al., supra*, which adopted the standard of review employed below.